

APR 07 2003

January 2, 2003



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Subject: 510 (K) SUMMARY**510 (K) Number:** _____**AmeriWater Contact:** Brian R. Bowman, Quality Manager

Proprietary Name: Portable RO+ Model MROS09
Common Name: Water Purification System
Classification Name: Water Purification System for Hemodialysis
Classification: Class II Medical Device under §876.5665

Device Description / Intended Use:

The AmeriWater Portable RO+ Model MROS09 is a portable, stand-alone water treatment system for use in hemodialysis applications. It is designed to pre-treat and purify potable water for use in making dialysate for hemodialysis. The AmeriWater Portable RO+ Model MROS09 is intended to be used in hospitals, clinics, home-care, and dialysis centers. It provides quiet operation for bedside use and may be used for acute care cases, small dialysis wings in hospitals, or to handle extra patients at dialysis centers. The RO+ is designed to produce water that meets or exceeds ANSI/AAMI RD62 requirements.

The water treatment components for the AmeriWater Portable RO+ Model MROS09 consist of a temperature-blending valve, two backwashing carbon filters, regenerating water softener with brine tank, a micron prefilter, and a reverse osmosis membrane. The components are conveniently packaged in ABS cabinets designed to fit in a standard washing machine pan. All components are constructed of materials that meet FDA and/or NSF standards.

The temperature-blending valve provides a constant feed water temperature of 77° F, the ideal operating temperature for reverse osmosis. The blend valve assembly is sized to accommodate all anticipated ranges of flow rates. It includes a check valve to prevent backflow of water into the hot and cold water lines and a thermometer for use in monitoring the operation and effectiveness of the temperature-blending valve.

The backwashing carbon filters are designed to remove chlorine, chloramines, and organics from the potable tap water as a means of pre-treatment before the reverse osmosis process.

The filters are in a worker/polisher series with a test port between the two filters. The carbon media is granular activated carbon with an iodine number greater than 900. The backwashing carbon filtration has been designed to meet all standards for carbon filtration as defined by the Association for the Advancement of Medical Instrumentation (AAMI). The backwash control dials are accessible externally and appropriately labeled to provide simple operation for the user. Backwashing should be completed after each treatment.

The regenerating water softener is designed to remove hardness from the water feeding the reverse osmosis process. The softener incorporates a control valve with a manual timer for regeneration. The control dials are accessible externally and appropriately labeled to provide simple operation for the user. The softener resin is an ultra high capacity, gel type, sulfonated polystyrene cation resin that provides superior service runs and longer life. Regenerations should be completed after each treatment.

The micron pre-filter is encased in an opaque polypropylene housing. The filter cartridge is a polylspun, dual open-end cartridge designed to filter sediment and carbon fines from the water feeding the reverse osmosis machine with greater than 80% efficiency. The user has the option of selecting a 1 micron or 5 micron filter cartridge.

The reverse osmosis membrane is a thin film, semi-permeable membrane that removes contaminants from the water by a separation process called reverse osmosis (RO). In this process the water is permitted to pass through the semi-permeable membrane, leaving behind the dissolved solids. This is accomplished by applying a pressure greater than the osmotic pressure difference to the concentrate water, which causes the direction of water passage through the membrane to reverse. In reverse osmosis the water travels from the more concentrate side of the membrane to the less concentrate side. Contaminants are removed from the water at a rejection rate greater than or equal to 94% to achieve product water that meets or exceeds ANSI/AAMI RD62 standards.

Substantial Equivalence:

The AmeriWater Portable RO+ Model MROS09 is the same in function and design as the AmeriWater Portable RO+ currently approved for market under the 510(k) number K924695. The basic design, intended use, and performance specifications remain the same for the new model of the RO+ product line. The changes in design that make this model different from the existing models are:

- the addition of backwashing carbon filters in place of the carbon exchange tank; and
- the addition of a regenerating water softener in place of the existing antiscalant system.

The backwashing carbon filters and regenerating water softener are manufactured to the same design and specifications as the backwashing carbon filters and regenerating water softeners approved for market with the AmeriWater Purification System for Hemodialysis under 510(k) number K991519.

Both the AmeriWater Portable RO+ (K924695) and the AmeriWater Portable RO+ Model MROS09 incorporate carbon filtration, water softening, micron pre-filtration, and reverse osmosis in the design. The technological characteristics and performance specifications for the device do not change in the new model. Carbon filtration is accomplished by a single carbon exchange tank in the Portable RO+ (K924695) currently marketed. The carbon tank performance is monitored daily and the tank is replaced when exhausted or at least every six months. In the new model, MROS09, the carbon filtration consists of two backwashing carbon filters with manual timers. The carbon filters are manually set to backwash after each treatment. The design and performance specifications for the backwashing carbon filters are the same as those used for the carbon filters currently marketed with the AmeriWater Purification System for Hemodialysis under 510(k) number K991519.

The AmeriWater Portable RO+ (K924695) accomplishes water softening with an onboard antiscalant system designed to bind the hardness ions so that they can be removed without scaling the reverse osmosis membrane. Model MROS09 utilizes a regenerating water softener that removes hardness from the water by a process called ion exchange. The regenerating water softener is designed with a manual timer for regeneration and is manually set by the user to regenerate after each treatment. The design and performance specifications for the regenerating water softener are the same as those used for the water softeners currently marketed with the AmeriWater Purification System for Hemodialysis under 510(k) number K991519.

In summary, the new model in the AmeriWater Portable RO+ line (Model MROS09) combines the technology of the portable reverse osmosis machine that is currently marketed under 510(k) number K924695 with the technology of the regenerating water softener and backwashing carbons currently marketed with the AmeriWater Purification System for Hemodialysis under 510(k) number K991519. There are no new technological characteristics and no new issues of safety or effectiveness raised by this design.

Prepared By:

Handwritten signature of Brian R. Bowman, dated 1/2/03.

Brian R. Bowman, 1/2/03
Quality Manager



APR 07 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Brian R. Bowman
Quality Manager
AmeriWater
1257 Stanley Avenue
DAYTON OH 45404

Re: K030059
Trade/Device Name: Portable RO+ Model MROS09
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: January 2, 2003
Received: January 7, 2003

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



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510 (K) Number: R030059

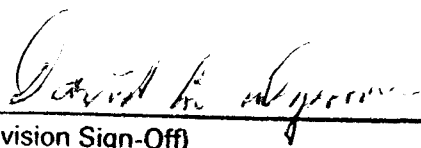
Device Name: Portable RO+ Model MROS09

STATEMENT OF INTENDED USE

The AmeriWater Portable RO+ Model MROS09 is a stand-alone water treatment system for use in hemodialysis applications. It is designed to pretreat and purify potable water for use in making dialysate for hemodialysis. The AmeriWater Portable RO+ with Onboard Pretreatment System is intended to be used in hospitals, clinics, home-care, and dialysis centers. It provides quiet operation for bedside use and may be used for acute care cases, small dialysis wings in hospitals, or to handle extra patients at dialysis centers.

*Note: Federal Law restricts this device to sale by or on the order of a physician for use as a water treatment device for hemodialysis.

Prescription Use 1


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number R030059